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✓ FUNGICIDES AND THE MILLER PESTICIDE
CHEMICALS AMENDMENT* ✓

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It is a pleasure to meet with you today to discuss the effect of the pesticide chemicals amendment on the use of fungicides.

The Food and Drug Administration, which I represent, enforces Federal laws that regulate the shipment of food from one State to another. The principal law is the Food Drug and Cosmetic Act of 1938. As originally enacted, it provided a method for determining whether a residue of a fungicide (or other pesticide) is necessary on food, and if it is, what quantity may remain without hazard to man. This was the old public hearing procedure.

In 1950 the Food and Drug Administration held spray residue hearings under this procedure to establish safe tolerances for pesticides then in common use. The hearings were not very satisfactory to government or agriculture. They were cumbersome, and the tolerances were not established for a long time after the hearings closed.

So now legislation was sponsored by Congressman A. L. Miller and others to set up an improved method for determining how much pesticide may remain on a crop when it is marketed. It was enacted into law in July 1954, and is referred to commonly as the Miller pesticide chemicals amendment to the Food Drug and Cosmetic Act.

It sets up more convenient procedures than were available before. It recognizes that sprays and dusts are necessary to assure a continuing supply of high quality foods in this country, and is designed to permit the effective use of these materials in the production of food without hazard to the consumer.

Very briefly, the new law works this way: A manufacturer of a pesticide (or some other person) submits a request or petition to the Food and Drug Administration asking for the establishment of a safe tolerance for residues of a chemical on specific crops on which it is to be used. With this request, he furnishes information about the toxicity of the residues when they are consumed over the life span of test animals such as rats or dogs. He furnishes information about the quantity of residue that remains. He asks the Department of Agriculture to certify that the pesticide chemical is useful in agriculture. When this certificate is available, the Commissioner of Food and Drugs publishes a regulation which states the amount of pesticide residue that can remain legally in or on the specified crops. That is, the regulation states the tolerance for the residue.

*Paper presented to Fungicide Colloquium, American Phytopathological Society, Atlanta, Georgia, December 28, 1955.



Some people are under the impression that this new law sets up a new requirement about pesticides in food -- that it will render crops in interstate commerce more likely to be seized by the Federal Government. But the new law does not change the basic requirement that foods in interstate commerce shall be free of dangerous quantities of spray residues. This requirement has been a part of the basic statute since 1938. What the new law does is to establish a more convenient method of determining what is a safe residue and announcing this tolerance level to the public.

The pesticide chemicals amendment will become fully effective for all fungicides next July. It is already effective for many of them, but there are extensions of the effective date for others.

Under this amendment all fungicides will fall in one of four classes:

1. Chemicals that are not considered poisonous as used on crops. Sulfur, lime sulfur, and the sodium and potassium analogues of lime sulfur are in this group.
2. Chemicals that are considered poisonous, but are used in agriculture so that their residues do not present any foreseeable hazard to man. These may be exempted from the requirement of a tolerance. Most of the common copper compounds have been exempted when they are used on growing crops before harvest. They are not exempted when applied at time of or after harvest.
3. Fungicides that are poisonous, but still are safe enough for small residues to remain in or on food without endangering the public health. Tolerances higher than zero are set for them on specific crops. Such tolerances have been set for:

Captan

Dinitro-O-cyclohexylphenol

Ferbam

Maneb

Zineb

Ziram

(And since Nabam is mixed with a zinc salt before use, forming Zineb, the tolerance for Zineb permits Nabam to be used too.)

Glyodin

Phygon

4. Chemicals that have a zero tolerance or its equivalent. Any compound not covered in one of the first three groups will have the equivalent of a zero tolerance when the law becomes fully effective. As a result of the 1956 spray residue hearings we found that -

Dinitro-O-cresol

Dinitro-O-sec-butylphenol and

Mercury containing compounds

are so toxic that if they are used, they should be used so that no residues remain at harvest.



Other fungicides in this fourth group have the equivalent of a zero tolerance because no higher tolerance has been established for them, and they have not been exempted from the requirement of a tolerance. These compounds are:

- Antibiotics for use on plants
- Formaldehyde
- Isothiocyanates
- Quaternary ammonium compounds
- Sporgon
- Sodium pentachlorophenate
- Thiram

Chemicals with zero tolerances may be used under proper conditions that leave no residues. Many of them are being used. Formaldehyde, sporgon, and thiram are used for seed treatment. Broad spectrum antibiotics are used early in the season to control fungus diseases where the time between application and harvest is enough to guarantee their complete removal from the plant.

There is another group of fungicides for which the effective date of the law has been extended. Diphenyl and O-phenylphenol are in this group. A petition already has been filed for O-phenylphenol, and we understand that a petition will be filed for a tolerance for diphenyl. These chemicals will be in one of the first four groups when the petitions are processed.

Where does this leave the plant pathologist who must recommend fungicides for use on crops during the 1956 growing season? In answering this question it will be wise to review recent developments in pesticide regulation. In 1947 the Federal Insecticide, Fungicide and Rodenticide Act became law. It requires economic poisons, a term that includes fungicides, to be registered by the Department of Agriculture before they are shipped interstate. Before registering a fungicide that Department determines that it is biologically effective and that the label has proper directions for use and adequate warnings to protect the operator of the spray rig. But the Department of Agriculture went farther. It asked the Food and Drug Administration to consider the toxicity and residue data submitted with a new chemical, and state whether the proposed directions for use would be apt to leave hazardous residues on food crops. We were glad to cooperate. For several years now the Department of Agriculture has given us a chance to comment on new pesticides before it registered them. Sometimes we have recommended that labels not be registered if there were evidence that proposed directions would leave potentially harmful residues, or if there were not enough data to permit a sound opinion. Thus, as the labels were registered in recent years, the requirements of the food laws have been considered.

The formal tolerances we have been establishing are, for the most part, the same as the old informal tolerances we had when making recommendations to the Department of Agriculture.

Now back to the question: During the coming growing season the plant pathologist can recommend fungicide uses that appear on labels currently registered with the Department of Agriculture. These uses should leave residues that are safe and meet the formal tolerances established under the Federal Food Drug and Cosmetic Act.



Where does the grower stand under the new law? Growers must understand that it is not safe for them to experiment with new pesticides on crops. They should use the materials according to label directions - on the crops specified, in the amounts specified, and at the times specified.

But the need for ordinary prudence in the use of fungicides should not alarm the consuming public or the growers. When a tolerance is established by the Federal Government, it means that -

1. Crops should bear no more than the tolerance level of residue.
2. The fungicide can be employed usefully in agriculture; this has been established by the certificate of approval as furnished the Food and Drug Administration by the Department of Agriculture.
3. Residues up to the tolerance level are safe; this has been established by adequate experimental studies on animals.
4. When the pesticide is used properly it will leave residues that are within the permitted level; it will not cause a tolerance unless there is evidence that it can be done.

We have been asked a number of questions recently about how the Food and Drug Administration enforces the Federal Food, Drug, and Cosmetic Act with regard to spray residues. Our procedures, broadly speaking, are as follows:

Before the growing season, we try to keep our finger on the development with regard to pesticides and new recommendations in spray residues from the States. During the growing season, inspectors in growing areas are in touch with State authorities and growers to determine what crops and areas are being used and how. The inspectors may pick up a few samples from farms or from shipping points for examination. These examinations might be to confirm earlier observations made during the growing season about the likelihood of high spray residues.

Then during the shipping season, some samples will be collected at shipping points and at destination for further examination for spray residues. When we go into a growing area to make investigations, we will, of course, still cooperate with the State and local agricultural authorities, and will endeavor to be helpful in connection with our inspectional activities. Unfortunately, our laboratory facilities are extremely limited. We are not able to run samples for spray residues for all who would like to have such tests made on their crops; however, if the samples that we collect to confirm our inspectional observations show high residues before a crop has been placed in interstate commerce, we will get in touch with the appropriate State authorities immediately so that steps may be taken to reduce the residues prior to shipment.





